

FRIDAY, DECEMBER 23, 1977

PART VI



ENVIRONMENTAL PROTECTION AGENCY

TOXIC SUBSTANCES CONTROL

Inventory Reporting Requirements

[6560-01]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL
PROTECTION AGENCYSUBCHAPTER R—TOXIC SUBSTANCES
CONTROL

[OTS-081002A; FRL 817-1]

PART 710—INVENTORY REPORTING
REGULATIONSAGENCY: Environmental Protection
Agency.

ACTION: Final rules.

SUMMARY: This notice promulgates the inventory reporting regulations proposed on March 9 and August 2, 1977 in the *FEDERAL REGISTER* and supplemented thereafter. Specifically, these regulations require some persons who manufacture or import chemical substances:

(1) To report the identity of each chemical substance manufactured at each site of manufacture, or imported into the United States, for a commercial purpose;

(2) To estimate the amount of each chemical substance manufactured at each site, or imported during calendar year 1977; and

(3) To indicate whether each such chemical substance is manufactured and used only within one site.

Based upon the reports of manufacturers and importers, EPA will publish an initial inventory of chemical substances. After publication of the initial inventory, these regulations authorize reporting by processors of additional chemical substances. EPA will publish a revised inventory including these substances in 1979.

DATES: These regulations are effective January 1, 1978. Reporting for the initial inventory by manufacturers and importers of chemical substances will begin January 1, 1978 and end May 1, 1978. During the 210 days after publication of the initial inventory in late 1978, processors of chemical substances, and importers of chemical substances as part of mixtures or articles, may report additional chemical substances for a revised inventory. (NOTE: Many of the terms used in these regulations, such as "manufacturer" and "processor" have a special meaning for purposes of these regulations. Persons should read the regulations, especially the definition section carefully, and be sure they understand the special meanings of these terms.)

FOR FURTHER INFORMATION CON-
TACT:

Mr. John B. Ritch, Jr., Director, Office of Industry Assistance, Office of Toxic Substances (TS-788), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, 202-755-0535. To obtain reporting forms and instructions, call this toll-free number 800-424-9065.

SUPPLEMENTARY INFORMATION: The regulations are promulgated under the authority of subsection 8(a) of the Toxic Substances Control Act (90 Stat. 2003; 15 U.S.C. 2601 et seq.) hereinafter referred to as TSCA.

On March 9, 1977, EPA first published in the *FEDERAL REGISTER* (42 FR 13130) proposed inventory reporting regulations to govern reporting of chemical substances required by subsection 8(a) of TSCA. On April 12, 1977, EPA published a supplemental notice of proposed rule-making in the *FEDERAL REGISTER* (42 FR 19298) providing additional information pertaining to the proposed inventory regulations. This notice set forth instructions for use of a Candidate List of Chemical Substances and specified minerals which EPA proposed to include in the inventory of chemical substances.

On April 18, 1977, EPA held a public meeting in Washington, D.C. to provide interested persons an opportunity to comment publicly on the proposed regulations. On April 28, 1977, EPA published a notice of availability of the Candidate List of Chemical Substances for use in reporting chemicals for inclusion on the inventory (42 FR 21639). On July 8, 1977, the Agency published a notice to amend the procedures for securing a copy of the Candidate List on computer-readable tape (42 FR 35183). EPA is preparing to supplement the Candidate List with at least one additional list of substances. As soon as any supplementary list is available, EPA will publish a notice of availability in the *FEDERAL REGISTER* to enable persons to request copies.

On August 2, 1977, EPA repropoed the inventory reporting regulations. In order to provide interested persons an opportunity to comment publicly on the proposed regulations, EPA held a public meeting in Washington, D.C. on August 24, 1977. A transcript of the public meeting is available for public inspection in the Office of Toxic Substances at the address provided above. Finally, on October 3, 1977, EPA published a supplementary notice to the August 2 proposal. This notice clarified the applicability of the reporting regulations to importers and invited comment on draft reporting forms.

EPA has received over 400 comments in response to the notices of proposed rule-making published on March 9, August 2, and October 3, 1977. These comments were received from trade associations, business firms, environmental organizations, labor unions, state and federal agencies and others. Appendix A of this notice summarizes and responds to the significant issues raised in these comments. The major issues that were resolved in promulgation of these final regulations are discussed below.

Appendix B of these regulations includes copies of the reporting forms for these regulations. These forms are published here as samples of the official forms which will be available from EPA. These forms may not be used for reporting. The official forms, which will be distributed to persons included on EPA's mailing list, each has a unique identifying number for purposes of processing.

AUTHORITY, PURPOSE AND SCOPE OF THE
REGULATIONS

These regulations are promulgated pursuant to the authority of section 8(a)

of TSCA. They accomplish two of the purposes contained in that section of the Act. In the first place, in accordance with section 8(a) (1) of the Act, they require reporting for compilation of the inventory of chemical substances manufactured or processed for a commercial purpose in the United States. The Administrator is required to compile and publish an inventory of chemical substances under section 8(b) of the Act. In the second place, under the authority of TSCA section 8(a) (1) (A), these regulations require reporting of production and site information on chemical substances, which is reasonably necessary for establishing a profile of the chemical industry, monitoring chemical substances in the environment, and setting Agency priorities for implementing other provisions of TSCA.

In the interest of accomplishing these objectives, § 710.3(a) requires any person who manufactured or imported chemical substances during calendar year 1977 to report concerning all such substances if (a) thirty percent or more of the weight of the products consists of products of the types described under Standard Industrial Classification (SIC) groups 28 or 2911, or (b) if the total pounds of reportable chemical substances manufactured or imported equals one million pounds or more. In addition, any person who manufactured at a site or imported a chemical substance in 100,000 pound quantities or greater during calendar year 1977 must report concerning that chemical substance.

By directing the reporting requirements to those persons who are significantly engaged in manufacturing chemical substances, EPA will create a profile of the chemical industry useful in future implementation of TSCA. As a minimum, the Agency will know the site of manufacture of all chemicals manufactured in quantities greater than 100,000 pounds. Moreover, for every plant site substantially engaged in producing chemical substances or chemical products for commercial purposes, EPA will know the identities of the substances manufactured there and the relative quantities in which they are produced.

As discussed further in the response to comments (Appendix A), EPA desires to minimize duplicative reporting to the extent consistent with its needs in implementing TSCA. Manufacturers and importers who do not meet the criteria for required reporting do not need to report individually. Instead, they may report through a trade association or rely upon another manufacturer or an importer to report the substances for inclusion on the inventory. Further, in the interest of minimizing duplicative reporting, persons who are processors of a chemical substance they neither manufacture nor import are not subject to the initial reporting requirements. Persons who process or use chemical substances for commercial purposes may report those chemical substances not included in the initial inventory during a special reporting period. In addition, persons who im-

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port chemical substances as a part of a mixture or article may report during the special reporting period. EPA expects to publish a revised inventory based on these additional reports sometime in fall 1979.

SMALL MANUFACTURER

As provided in TSCA section 8(a) and discussed in the preamble to the August 2 proposal, EPA may require "small manufacturers" to submit only information necessary for compilation of the inventory or concerning a chemical substance which is subject to a proposed rule or order under TSCA section 4, 5 or 6 or court action under section 5 or 7. At this time, any person who is required to report and who is a small manufacturer is only required to submit information required for compilation of the inventory. Accordingly, any "small manufacturer" need only identify chemical substances and report certain limited information required for purposes of the inventory. Small manufacturers are exempt from reporting production volumes and, if a small manufacturer has more than one plant site, he need not separately report for each site. Since these regulations define "manufacture" to include "import," the provision applies equally to "small importers."

The definition of "small manufacturer or importer" proposed in August has been revised to exempt from these additional reporting requirements those manufacturers and importers with total sales of less than \$5 million. This exemption, however, does not apply with respect to any chemical substance produced by a manufacturer at one site or imported in quantities equal to or greater than 100,000 pounds during calendar year 1977. Accordingly, no manufacturer will be considered a "small manufacturer or importer" with respect to any chemical substance manufactured at one site or imported in quantities over 100,000 pounds.

In deciding how to define "small manufacturer or importer," EPA considered both the relative burden to manufacturers and importers to submit additional information and the value of that information to EPA and other federal agencies. Under this definition, the total cost of reporting for the inventory for the marginal small firm, in most cases, will be about 1 percent of profits. While the firms exempted under this definition represent nearly 80 percent of chemical firms, they account for only 4 percent of sales of chemical substances and only 6 percent of employment in SIC groups 28 and 2911.

In the interest of creating a data base that is at least complete with respect to the volumes of those chemical substances produced in substantial quantities, this definition does not exempt any manufacturer or importer from reporting the volumes of individual substances produced in quantities of over 100,000 pounds during calendar year 1977. Reporting production volume will involve simply providing the digit that is associated with a broad range (e.g., "4" is for production between 1 million and 10 million pounds),

as provided in the table at § 710.5(d) (4). Since the manufacturer or importer will already be reporting the names of substances, the additional burden of supplying production information in terms of large ranges should be minimal, especially for substances produced in significant quantities.

REPORTING SCHEDULE AND ENFORCEMENT

These regulations provide for publication of an initial inventory based on reporting by manufacturers and importers of chemical substances, followed by publication of a revised inventory based on reporting by processors of chemical substances and importers of chemical substances as part of mixtures and articles. Reporting for the initial inventory will begin on January 1, 1978, and end May 1, 1978. Manufacturers and importers of chemical substances must report, as provided in § 710.3(a), during this first reporting period. Processors are only subject to the second reporting period which will begin after publication of the initial inventory and end 210 days later.

Thirty days after publication of the initial inventory, premanufacture notification will begin. After that date, any person who intends to manufacture or import (in bulk) a chemical substance not included on the inventory must submit premanufacture notice under section 5 (a)(1)(A). Processors and users of a chemical substance for a commercial purpose, and importers of a chemical substance as a part of a mixture or article will be able to supplement the initial inventory during the second reporting period, as provided in § 710.3(b).

TSCA section 15(1) makes it unlawful for any person to fail or refuse to comply with the premanufacture notification requirements of section 5. TSCA section 15(2) makes it unlawful for a person to use for a commercial purpose any substance which he had reason to know was manufactured in violation of section 5. Sections 15(1) and 15(2) as they relate to section 5(a)(1)(A) will not be applied to persons who process or use for a commercial purpose chemical substances not on the inventory or who import chemical substances as a part of a mixture until after publication of the revised inventory. By reporting any chemical substance, not included on the initial inventory during the second reporting period, these persons will be able to protect themselves from prosecution under section 15(2) with respect to the requirements of section 5(a)(1)(A) of TSCA. Importers of a chemical substance as part of a mixture or article will not be subject to premanufacture notification requirements for "new" chemical substances until 30 days after publication of the revised inventory. Under these reporting requirements, persons who import chemical substances as part of articles do not have to report concerning those chemical substances for the initial inventory. EPA is still considering whether importers of certain chemical substances as part of articles will be subject to premanufacture notification requirements under section 5(a)(1)(A).

EPA will address this issue prior to publication of the initial inventory. Refer to comments 18 to 23 for further clarification of these issues concerning importers of chemical substances.

Finally, EPA recognizes that it is inevitable, considering the large volume of information to be compiled and transmitted, that there may be some unintentional clerical errors in reporting. Accordingly, the note in § 710.1(b) of these regulations provides that EPA does not intend to focus its enforcement efforts on reporting violations that are clerical in nature. Instead, EPA will give priority to bringing actions against persons who (1) report false information, (2) report for inclusion on the inventory chemical substances which are excluded under section 710.4(c) of these regulations, (3) fail to report, or (4) fail to maintain records documenting reported information.

CONFIDENTIALITY

As discussed in the preamble to the August proposal, there is an apparent conflict between section 14 and sections 8(b) and 5(a) of TSCA with respect to the inclusion of the identities of certain chemical substances on the inventory. Section 8(b) requires EPA to publish a list of "each chemical substance which is manufactured or processed in the United States. Such list shall include each chemical substance which any person reports, under section 5 or subsection (a) of this section, is manufactured or processed in the United States." (emphasis added) The list has two purposes, to inform the public concerning which chemical substances are manufactured or processed for a commercial purpose and to which the public may be exposed, and to define what constitutes a "new chemical substances" for purposes of premanufacture notification requirements under section 5(a). However, section 14 states that any information reported to EPA under TSCA that is exempt from disclosure under the Freedom of Information Act fourth exemption (5 U.S.C. 552(b)(4)) may not be disclosed except in specific circumstances set out in section 14 (a) and (b).

In the absence of the requirements of section 8(b) and 5(a), EPA would publish an inventory that would not include the identities of specific chemical substances for which the fact that the particular substance is manufactured or processed for commercial purposes is confidential. In the absence of the requirements of section 14, EPA would publish a list of all chemical substances manufactured or processed for commercial purposes. Since the term manufacture includes "to import", this discussion and the regulations apply equally to imported chemical substances.

Having no explicit statutory guidance about how to resolve this conflict, EPA has attempted to balance the concerns of section 14 with those of sections 8(b) and 5(a). EPA believes that Congress did not intend manufacturers to be required to furnish EPA premanufacture notification on existing chemical substances whose identities for purposes of the in-

ventory have been claimed as trade secret. EPA believes that Congress did intend EPA to preserve confidentiality to the maximum extent practicable without impairing administration of TSCA. Accordingly, EPA has developed the approach set forth in § 710.7, and explained in greater detail in Appendix A, Response to Significant Comments. The approach balances confidentiality under section 14 with the regulatory scheme of sections 8(b) and 5(a). This approach will be used for the submission of confidential identities for the inventory now under section 8(a) and subsequently under section 5(a)(1)(A). Should the approach fail to achieve its stated purposes, EPA will re-examine the approach and consider alternatives.

EPA will allow manufacturers, importers and processors to claim as confidential the fact that a particular chemical substance is manufactured or processed in the United States for commercial purposes. The manufacturer or processor making such a claim must provide certain information and agree to certain provisions specified in § 710.7(e) of these regulations. EPA will make a final determination concerning entitlement to confidentiality, in accordance with EPA's procedures for handling confidentiality of business information in 40 CFR Part 2, Subpart B (41 FR 36906, September 1, 1976). If EPA determines that the fact the particular chemical substance is manufactured or processed in the United States for commercial purposes is confidential, EPA will not place the specific chemical identity on the published inventory. Instead, EPA will publish a generic chemical name in an appendix to the inventory.

The generic chemical name will inform the public of at least the generic types of confidential chemical substances manufactured or processed for a commercial purpose in the United States. Further, the generic name will be helpful to manufacturers who consult the appendix to the inventory to determine whether they must submit premanufacture notification under section 5(a)(1)(A) for a proposed "new" chemical substance. The generic name will alert them to the possibility that the proposed "new" chemical substance may be included on the inventory under that name. The generic name will not establish a category of chemical substances for purposes of the inventory and premanufacture notification requirements.

EPA wants to avoid the anti-competitive impacts which may arise if new entrants into an existing market were required to give premanufacture notification while the existing manufacturer who claimed the identity of the chemical substance as confidential was able to continue to manufacture it. If a manufacturer is required to give premanufacture notification on a chemical substance, he cannot manufacture the substance for at least the 90-day notice period. This delay may be considerably longer if a testing rule under section 4 requires the manufacturer to develop and submit certain test data. EPA is also

interested in distinguishing a "fishing expedition" by a competitor from a *bona fide* inquiry concerning the identities of confidential chemical substances on the inventory.

Accordingly, § 710.7(g) permits an inquiring manufacturer to submit certain information to establish his *bona fide* intent to manufacture the chemical substance. A manufacturer is not required to establish this intent; he can simply submit a premanufacture notification. If a manufacturer establishes *bona fide* intent to manufacture a chemical substance, EPA will tell the inquiring manufacturer whether the chemical substance is included on the inventory as a confidential identity, and therefore, whether he must submit premanufacture notification under TSCA section 5(a)(1)(A). The submitter who claimed that the specific chemical identity should not appear on the inventory will be required by § 710.7(e)(2) to agree to have available and furnish to EPA upon request certain identifying information on the chemical substance and agree that EPA may disclose to a person with a *bona fide* intent to manufacture the substance whether the particular chemical substance is included on the inventory. Failure to furnish this information to EPA upon request will be construed as a waiver of the claim of confidentiality, and the specific identity will be placed on the inventory. The Agency believes that this resolution of the conflict between sections 5(a), 8(b), and 14 of the statute balances the equities and interests of all parties.

There are several other issues concerning confidentiality that have been raised by these regulations. These issues and further elaboration of the above approach are discussed in Appendix A, Significant Comments and Responses.

DEFINITIONS

EPA wishes to emphasize that the terms used in these regulations may not be wholly consistent with the ordinary usage of such terms. For example, the term "manufacturer" includes importers. As used in these regulations, the terms "manufacturer" and "processor" may both apply to a person who normally would consider himself one or the other. "Intermediate" refers only to those intermediates which are isolated or removed from the equipment in which they are manufactured. Persons should be sure they understand the special meanings of the terms used for purposes of these regulations.

OFFICIAL RECORD OF RULEMAKING

TSCA section 19(a)(3) defines the term "rulemaking record" for the purposes of judicial review of a section 8(a) regulation as (1) the rule being reviewed, (2) any written submission of interested parties respecting the promulgation of such rule and (3) any other information which the Administrator considers to be relevant to such rule and which the Administrator identified on or before the date of the promulgation of such rule, in a notice published in the FEDERAL REGISTER.

Accordingly, TSCA requires the Agency to publish in the FEDERAL REGISTER the list of documents that constitute the record of this rulemaking. Public comments are exempt from FEDERAL REGISTER listing under section 19(a)(3) and have not been listed. A full listing of the public comments is available on request from the Record and Hearing Clerk. In addition, those documents listed below as part of this rulemaking record are available at the Office of the Record and Hearing Clerk in the Office of Toxic Substances.

The factual and policy considerations that are the basis of this rule were published in the preambles to the March 9 and August 2, 1977 proposed rules and October 3, 1977 supplemental notice. In response to public comment, EPA has prepared a document analyzing the impacts of these regulations which the Administrator hereby identifies under TSCA section 19(a)(3)(E) as part of the record of this rulemaking. This document surveys information generally available to the public. It is entitled, "Analysis of Options for Definition of Small Business and Estimated Cost of the Initial Section 8(a) Reporting Requirements," prepared by Arthur D. Little, Inc., Cambridge, Massachusetts, contract number 68-01-4381 (November 1977).

During development of this rule, EPA has conducted two public meetings and several informal meetings attended by interested members of the public. Transcripts of the three public meetings and minutes of several informal meetings are hereby included under section 19(a)(3)(e) as part of this rulemaking.

1. Transcript of public meeting on TSCA Inventory Reporting Regulations as proposed, March 9, 1977—(April 18, 1977).

2. Transcript of public meeting on TSCA Inventory Reporting Regulations, as proposed August 2, 1977—August 24, 1977).

Informal meetings were held with interested members of industry, labor, and environmental groups on the following dates. Minutes of these meetings are included in the record.

December 13, 1976	May 6, 1977
December 21, 1976	May 17, 1977
January 6, 1977	June 9, 1977
January 7, 1977	August 4, 1977
January 19, 1977	August 18, 1977
April 14, 1977	September 30, 1977
April 21, 1977	October 6, 1977
April 27, 1977	October 31, 1977

Transcripts of the informal meetings held May 6 (with the American Importers Association) and May 17 (concerning confidentiality) are also included in the record.

In addition, during the development of these rules, Agency staff members had phone conversations with interested members of the public. Phone conversations relevant to this rulemaking are included in the record of this rulemaking. A listing of these materials is available upon request from the Record and Hearing Clerk.

EFFECTIVE DATE

These regulations shall take effect on January 1, 1978. In accordance with 5 U.S.C. 553(d)(3), the Administrator finds for good cause that the effective date of these regulations will not be postponed until 30 days after publication in the FEDERAL REGISTER. TSCA section 8(b) provides that a chemical substance may be included on the inventory only if it was manufactured or processed within three years before the effective date of these regulations. If these regulations are effective on January 1, 1978, any chemical substance manufactured or processed for a commercial purpose since January 1, 1975 may be reported for the inventory. The January 1, 1975 date has been relied on by the industry in preparing for reporting under these regulations. Any greater delay in the effectiveness of these regulations would interfere with orderly and timely reporting for the inventory.

ECONOMIC IMPACT ANALYSIS STATEMENT

EPA has determined that the regulation does not require the compilation of an Economic Impact Analysis Statement as required by Executive Order 11821. This determination is based on the cost estimate prepared by Arthur D. Little, Inc., as part of their report, "Analysis of Options for Definition of Small Business and Estimated Cost of the Initial Section 8(a) Reporting Requirements," (November 1977), which is part of the rulemaking record. The total cost to industry of complying with the requirements of this regulation does not exceed \$15 million. Accordingly, EPA has not performed an Economic Impact Analysis because the cost does not exceed the criteria for a major Agency action.

The Environmental Protection Agency has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Analysis Statement Under Executive Order 11821 and OMB Circular A-107.

Dated: December 12, 1977.

DOUGLAS COSTLE,
Administrator.

Part 710 is established to read as follows:

- Sec.
- 710.1 Scope and compliance.
 - 710.2 Definitions.
 - 710.3 Applicability: Reporting for the initial and revised inventory.
 - 710.4 Scope of the inventory.
 - 710.5 How to report for the inventory.
 - 710.6 When to report.
 - 710.7 Confidentiality.
 - 710.8 Effective date.

AUTHORITY: Subsection 8(a), Toxic Substances Control Act (TSCA) (90 Stat. 2003, (15 U.S.C. 2607(a))).

§ 710.1 Scope and compliance.

(a) This Part establishes regulations governing reporting by certain persons who manufacture, import, or process chemical substances for commercial purposes under section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)). Section 8(a) authorizes the Admin-

istrator to require reporting of information necessary for administration of the Act and requires EPA to issue regulations for the purpose of compiling an inventory of chemical substances manufactured or processed for a commercial purpose, as required by section 8(b) of the Act. Following an initial reporting period, EPA will publish an initial inventory of chemical substances manufactured or imported for commercial purposes. After a supplemental reporting period, EPA will publish a revised inventory including those additional chemical substances processed or used for commercial purposes or imported for commercial purposes as a part of a mixture or article. Further, in accordance with section 8(b), EPA periodically will amend the inventory to include new chemical substances which are manufactured or imported for a commercial purpose and reported under section 5(a)(1) of the Act. EPA also will revise the categories of chemical substances and make other amendments as appropriate.

(b) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under these reporting regulations. In addition, section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by these regulations. Section 16 provides that any person who violates a provision of section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to section 17, the Government may seek judicial relief to compel submission of section 8(a) information and to otherwise restrain any violation of section 15.

NOTE.—As a matter of traditional Agency policy, EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.

(c) Each person who reports under these regulations shall maintain records that document information reported under these regulations and, in accordance with the Act, permit access to, and the copying of such records by EPA officials.

§ 710.2 Definitions.

For the purposes of this Part: (a) The following terms shall have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., and the regulations issued under such Act: "cosmetic," "device," "drug," "food," and "food additive." In addition, the term "food" includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 et seq.; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 et seq.; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 et seq.

(b) The term "pesticide" shall have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and the regulations issued thereunder.

(c) The following terms shall have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 et seq., and the regulations issued thereunder: "by-

product material," "source material," and "special nuclear material."

(d) "Act" means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.

(e) "Administrator" means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any other person who shall by operation of law be authorized to carry out such functions.

(f) An "article" is a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either, no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.4 (d)(5); except that fluids and particles are not considered articles regardless of shape or design.

(g) "Byproduct" means a chemical substance produced without separate commercial intent during the manufacture or processing of another chemical substance(s) or mixture(s).

(h) "Chemical substance" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that "chemical substance" does not include:

- (1) Any mixture,
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide,
- (3) Tobacco or any tobacco product, but not including any derivative products,
- (4) Any source material, special nuclear material, or byproduct material,
- (5) Any pistol, firearm, revolver, shells, and cartridges, and

(6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(i) "Commerce" means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce described in clause (1).

(j) "Distribute in commerce" and "distribution in commerce" when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture, mean to sell or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.

(k) "EPA" means the U.S. Environmental Protection Agency.

(l) "Importer" means any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the U.S. and includes: (1) The person primarily liable for the payment of any duties on the merchandise, or (2) an authorized agent acting on his behalf (as defined in 19 CFR 1.11).

(m) "Impurity" means a chemical substance which is unintentionally present with another chemical substance.

(n) "Intermediate" means any chemical substance (1) which is intentionally removed from the equipment in which it is manufactured, and (2) which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).

NOTE.—The "equipment in which it was manufactured" includes the reaction vessel in which the chemical substance was manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical substance may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.

(o) "Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

(p) "Manufacture or import for commercial purposes" means to manufacture or import:

(1) For distribution in commerce, including for test marketing purposes, or

(2) For use by the manufacturer, including for use as an intermediate.

(q) "Mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined and if, after the effective date of premanufacture notification requirements, none of the chemical substances comprising the combination is a new chemical substance, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.

(r) "New chemical substance" means any chemical substance which is not included in the inventory compiled and published under subsection 8(b) of the Act.

(s) "Person" means any natural or juridical person including any individual, corporation, partnership, or association, any State or political subdivision thereof, or any municipality, any interstate body and any department,

agency, or instrumentality of the Federal government.

(t) "Process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

(u) "Process for commercial purposes" means to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.

(v) "Processor" means any person who processes a chemical substance or mixture.

(w) "Site" means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site. For the purposes of imported chemical substances, the site shall be the business address of the importer.

(x) "Small manufacturer or importer" means a manufacturer or importer whose total annual sales are less than \$5,000,000, based upon the manufacturer's or importer's latest complete fiscal year as of January 1, 1978, except that no manufacturer or importer is a "small manufacturer or importer" with respect to any chemical substance which such person manufactured at one site or imported in quantities greater than 100,000 pounds during calendar year 1977. In the case of a company which is owned or controlled by another company, total annual sales shall be based on the total annual sales of the owned or controlled company, the parent company, and all companies owned or controlled by the parent company taken together.

NOTE.—The purpose of the exception to the definition is to ensure that manufacturers and importers report production volumes for all chemical substances which they manufactured at one site or imported in quantities equal to or greater than 100,000 pounds during calendar year 1977.

(y) "Small quantities for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product" (hereinafter sometimes shortened to "small quantities for research and development") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that (1) are no greater than reasonably necessary for such purposes and (2) after the publication of the revised inventory, are used by, or directly under the supervision of, a technically qualified individual(s).

NOTE.—Any chemical substances manufactured, imported or processed in quantities of less than 1,000 pounds annually shall be presumed to be manufactured, imported, or

processed for research and development purposes. No person may report for the inventory any chemical substance in such quantities unless that person can certify that the substance was not manufactured, imported, or processed solely in small quantities for research and development, as defined in this section.

(z) "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(aa) "Technically qualified individual" means a person (1) who because of his education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his supervision, (2) who is responsible for enforcing appropriated methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in clause (3) of this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in clause (1) of this paragraph.

(bb) "Test marketing" means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture or article in commerce.

(cc) "United States," when used in the geographic sense, means all of the States, territories, and possessions of the United States.

§ 710.3 Applicability: Reporting for the initial inventory and revised inventory: Who must report; who should report.

Based on reports from manufacturers and some importers of chemical substances, EPA will compile an initial inventory of chemical substances manufactured for commercial purposes. Paragraph (a) of this section identifies who must report for this initial inventory and who should report. After publication of the initial inventory, EPA will compile a revised inventory of chemical substances manufactured or processed for a commercial purpose based on reports from processors of chemical substances, and from importers of chemical substances as a part of mixtures or articles. Paragraph (b) of this section identifies who may report for this revised inventory. Paragraph (c) of this section identifies

the persons not subject to the initial inventory.

(a) *The initial inventory*—(1) *Domestic manufacturers who must report concerning chemical substances.* Any person who manufactured a chemical substance(s) in the United States for a commercial purpose during calendar year 1977 must report concerning:

(i) All chemical substances which that person manufactured in the United States during calendar year 1977 at each site for which:

(A) Thirty percent or more of the weight of the products distributed from that site consists of products of the types described under Standard Industrial Classification (SIC) Group 28 or 2911; or

(B) The total pounds of reportable chemical substances manufactured at that site equals one million pounds or more; and

(ii) Any chemical substance not reported under paragraph (a) (1) (i) of this section that was manufactured at a site during calendar year 1977 in quantities equal to or greater than 100,000 pounds.

NOTE.—Any person who is a "small manufacturer," as defined in § 710.2, and who has more than one site, is exempt from separately reporting the chemical substances manufactured at each site.

(2) *Importers who must report concerning chemical substances.* Any person who imported a chemical substance into the United States for a commercial purpose during calendar year 1977 must report concerning:

(i) All chemical substances which that person imported into the United States during calendar year 1977 if:

(A) Thirty percent or more of the weight of the products imported consists of products of the types described under Standard Industrial Classification (SIC) Group 28 or 2911; or

(B) The total pounds of reportable chemical substances imported equals one million pounds or more; and

(ii) Any chemical substance not reported under paragraph (a) (2) (i) of this section that was imported during calendar year 1977 in quantities equal to or greater than 100,000 pounds.

NOTE.—These reporting requirements include all chemical substances imported in bulk form, including in cans, bottles, drums, barrels, packages, tanks, bags and other containers, but do not include chemical substances imported as part of mixtures or articles.

(3) *Other manufacturers and importers who should report chemical substances.* (i) In order to ensure that a chemical substance is included in the initial inventory, any person who manufactures or imports, or who has manufactured or imported a chemical substance (including the importation of a chemical substance as part of a mixture or an article) for a commercial purpose since January 1, 1975, may report concerning that chemical substance.

(ii) Any person permitted to report under paragraph (a) (3) of this section may either report individually or, in

accordance with § 710.5(f), authorize a trade association or other agent to report on his behalf.

(b) *Revised inventory.* (1) During the reporting period for the revised inventory (§ 710.6(c)), a person may report concerning a chemical substance which was not included in the initial inventory if:

(i) The person has processed or used the chemical substance (including use in the manufacture of a mixture or article containing that chemical substance) for a commercial purpose since January 1, 1975; or

(ii) The person has imported the chemical substance as part of a mixture or article for a commercial purpose since January 1, 1975.

(2) Any person permitted to report under paragraph (b) of this section either may report individually or, in accordance with § 710.5(f), may authorize a trade association or other agent to report on his behalf.

NOTE.—The premanufacture notification requirements of section 5(a)(1)(A) of the Act for manufacturers of new chemical substances and importers of new chemical substances in bulk will begin 30 days after the publication of the initial inventory and will apply to all chemical substances not included in the initial inventory. The premanufacture notification requirements of section 5(a)(1)(A) will not be applied to importers of chemical substances as part of a mixture until 30 days after publication of the revised inventory. In addition, section 15(2) of the Act as it relates to section 5(a)(1)(A) will not be applied to persons who process or use for a commercial purpose chemical substances not on the inventory until after publication of the revised inventory.

(c) *Persons not subject to the initial inventory.* Persons who have only processed or used a chemical substance for a commercial purpose are not subject to the initial inventory requirements.

§ 710.4 Scope of the inventory.

(a) *Chemical substances subject to these regulations.* Only chemical substances which are manufactured, imported, or processed "for a commercial purpose," as defined in § 710.2, are subject to these regulations.

(b) *Naturally occurring chemical substances automatically included.* Any chemical substance which is naturally occurring and (1) which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or

(2) which is extracted from air by any means, shall automatically be included in the inventory under the category "Naturally Occurring Chemical Substances." Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

(c) *Substances excluded by definition or section 8 (b) of TSCA.* The following substances are excluded from the inventory:

(1) Any substance which is not considered a "chemical substance" as provided in subsection 3(2)(B) of the Act

and in the definition of "chemical substance" in § 710.2(h);

(2) Any mixture as defined in § 710.2(q);

NOTE.—A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term "mixture" includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.

(3) Any chemical substance which is manufactured, imported, or processed solely in small quantities for research and development, as defined in § 710.2(y); and

(4) Any chemical substance not manufactured, processed or imported for a commercial purpose since January 1, 1975.

(d) *Chemical substances excluded from the inventory.* The following chemical substances are excluded from the inventory. Although they are considered to be manufactured or processed for a commercial purpose for the purpose of section 8 of the Act, they are not manufactured or processed for distribution in commerce as chemical substances *per se* and have no commercial purpose separate from the substance, mixture, or article of which they may be a part.

NOTE.—In addition, chemical substances excluded here will not be subject to premanufacture notification under section 5 of the Act.

(1) Any impurity.

(2) Any byproduct which has no commercial purpose.

NOTE.—A byproduct which has commercial value only to municipal or private organizations who (i) burn it as a fuel, (ii) dispose of it as a waste, including in a landfill or for enriching soil, or (iii) extract component chemical substances which have commercial value, may be reported for the inventory, but will not be subject to premanufacture notification under section 5 of the Act if not included.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleansers or other housekeeping products, fuels and fuel additives, water softening and treatment agents, photographic, films, batteries, matches, and safety flares, and which is not itself manufactured for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints; or other chemical

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substances formed during manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that may occur as described elsewhere in this § 710.4(d).

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or de-foamer, dispersant, precipitation inhibitor, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended or (ii) a chemical substance, solely intended to impart a specific physicochemical characteristic, functions as intended.

(8) Chemical substances which are not intentionally removed from the equipment in which they were manufactured.

NOTE.—See note to definition of "intermediate" at § 710.2(n) for explanation of "equipment in which it was manufactured."

§ 710.5 How to report.

(a) *General instructions.* (1) Except for small manufacturers or small importers, any person who is required to report under § 710.3(a) (1) or (2) shall follow the reporting procedures of paragraphs (b), (c), and (d) of this section.

(2) Any person who reports under § 710.3(a)(3) shall follow the reporting procedures of paragraphs (b), (c), (d) (1) and (d) (3) of this section. In addition, the Agency encourages these persons to report in accordance with paragraphs (d) (2) and (d) (4) of this section. A trade association or other agent may report aggregated production data under paragraph (d) (4) of this section.

(3) Any person who is required to report under § 710.3(a) (1) or (2) and who is a small manufacturer or small importer as defined in § 710.2 shall follow the reporting procedures of paragraphs (b), (c), and (d) (1) and (3) of this section except that such person is exempt from reporting production volume (for quantities less than 100,000 pounds) and site information.

(4) Any person who reports under section 710.3(b) shall follow the reporting procedures of paragraphs (b), (c), and (d) (1) of this section.

(b) *Reporting the identity of a chemical substance.* (1) Any person reporting under these regulations should first read and carefully follow the reporting instructions, "Reporting for the Chemical Substance Inventory," published by and available through EPA.

(2) To report a chemical substance, a person should first consult the TSCA Candidate List of Chemical Substances and any amendment to the Candidate List. For assistance in using the Candidate List, consult the "Guide to the Use of the TSCA Candidate List of Chemical Substances."

(3) All persons required to report except "small manufacturers and importers" must use a separate Form A, B, or C to report chemical substances for each site. Small manufacturers and importers may report several chemical substances manufactured at different sites on one form, as appropriate.

(4) To report a chemical substance found in the Candidate List, or in an amendment to the list, a person must complete, sign, and submit EPA inventory report Form A (EPA Form No. 7710-3A). All forms, A through D, have OMB No. 1585 77011.

(5) To report a chemical substance not found in the Candidate List, or in an amendment to the list, but for which there is a Chemical Abstracts Service (CAS) Registry Number, a person must complete, sign and submit EPA inventory report Form B (EPA Form No. 7710-3B).

(6) To report a chemical substance which is not found in the Candidate List, or in an amendment to the list, and for which there is no known CAS Registry Number, a person must complete, sign, and submit EPA inventory report Form C (EPA Form No. 7710-3C). Persons must describe chemical substances on Form C as specifically as possible, in accordance with the instructions published by EPA, "Reporting for the Chemical Substance Inventory."

(7) To report a chemical substance whose chemical identity is claimed to be confidential, a person must complete, sign, and submit EPA inventory report Form C (EPA Form No. 7710-3C). In addition, he must substantiate the claim that the chemical identity is confidential at the time he submits the form to EPA, in accordance with instructions published in "Reporting for the TSCA Inventory" and section 710.7.

NOTE.—The reporting instructions also describe a reporting Form D (EPA Form No. 7710-3D). This is for additional voluntary reports which may be submitted by any person who manufactures trademarked products comprised of chemical substances and is not a substitute for any of the reports required by these regulations.

(c) *Reporting polymers.* (1) To report a polymer a person must list in the description of the polymer composition at least those monomers used at greater than two percent (by weight) in the manufacture of the polymer.

(2) Those monomers used at two percent (by weight) or less in the manufacture of the polymer may be included as part of the description of the polymer composition.

NOTE.—The "percent (by weight)" of a monomer is the weight of the monomer expressed as a percentage of the weight of the polymeric chemical substance manufactured.

(d) *Reporting other information concerning a chemical substance.* (1) For purposes of the initial inventory, designate whether the person manufactures and/or imports the chemical substance. For purposes of the revised inventory, designate whether the person processes and/or imports the chemical substance.

(2) Report the site(s) at which the person manufactures and/or imports the

chemical substance. The site, as defined in § 710.2(w), for importers is their business address.

(3) Designate whether the person manufactures and processes the chemical substances only within a site and does not distribute the chemical substance, or any mixture or article containing that substance, for commercial purposes outside that site.

NOTE.—This requirement does not apply to importers.

(4) Report the amount of the chemical substance which the person manufactured at each site and/or imported during calendar year 1977. For each substance, report the digit (e.g., 0 through 9) which corresponds to the appropriate volume range, according to the following table. Enter "N" in the space provided for production amounts if the person did not manufacture or import the substance during calendar year 1977. Small manufacturers or importers, as defined in § 710.2(x), should enter "X" in the space provided for production amounts of less than 100,000 pounds (45,400 kilograms). If a small manufacturer or importer reports these production amounts, that person shall enter both "X" and the appropriate digits (e.g., X0, X1, or X2). For other production ranges, do not include an "X" (e.g., 3 through 9). Trade associations or other agents should enter "A" in the space provided for production amounts. If trade associations or agents report production volumes, they should enter both "A" and the appropriate digits (e.g., A2 or A6).

(0) Less than 1,000 pounds; Less than 454 kilograms.

(1) 1,000 to 10,000 pounds; 454 to 4,540 kilograms.

(2) 10,000 to 100,000 pounds; 4,540 to 45,400 kilograms.

(3) 100,000 to 1 million pounds; 45,400 to 454,000 kilograms.

(4) 1 million to 10 million pounds; 454,000 to 4.54 million kilograms.

(5) 10 million to 50 million pounds; 4.54 million to 22.7 million kilograms.

(6) 50 million to 100 million pounds; 22.7 million to 45.4 million kilograms.

(7) 100 million to 500 million pounds; 45.4 million to 227 million kilograms.

(8) 500 million to 1 billion pounds; 227 million to 454 million kilograms.

(9) over 1 billion pounds; over 454 million kilograms.

(A) Trade associations or other agents.

(e) *Importers.* (1) Any importer who reports a chemical substance for the inventory may authorize the foreign supplier of the imported chemical substance(s) to report to EPA on his behalf, if both the foreign supplier and the importer sign the declarations provided on the reporting forms. A foreign supplier may authorize an agent to act in his behalf.

(2) The importer has the ultimate responsibility for reporting all information required by this Part and for the completeness and truthfulness of such information. If certain information is not or cannot be provided by the foreign supplier or his duly authorized agent, it must be provided by the importer.

(f) *Trade associations or other agents.*

(1) A trade association or other agent may report on behalf of any person who is not required to report for the initial inventory under § 710.3 (a) (1) and (a) (2). Accordingly, a trade association or other agent may report on behalf of a manufacturer or importer of a chemical substance who chooses to report under § 710.3(a) (3), or any processor or user of a chemical substance, or any importer of a chemical substance as part of a mixture or an article who chooses to report under § 710.3(b).

(2) For every chemical substance reported by a trade association or other agent under this section, at least one manufacturer, importer or processor must have certified to that agent, and be able to document to EPA, in accordance with § 710.1(c), that the chemical substance was manufactured, imported, or processed for a commercial purpose since January 1, 1975.

§ 710.6 When to report.

(a) All reports for the initial inventory shall be submitted by May 1, 1978.

(b) All reports concerning chemical substances which are manufactured or imported for a commercial purpose for the first time during the period from May 1, 1978 to the effective date of pre-manufacture notification requirements shall be submitted when such manufacturing or importation begins.

(c) All reports for the revised inventory shall be submitted within 210 days after publication of the initial inventory.

§ 710.7 Confidentiality.

(a) A manufacturer, importer, or processor may claim that for a particular chemical substance any or all of the following items of information submitted under this Part are entitled to confidential treatment:

- (1) Company name.
- (2) Site.
- (3) The specific chemical identity.
- (4) Whether the chemical substance is manufactured, imported, or processed.
- (5) Whether the chemical substance is manufactured and processed only within one site and not distributed for commercial purposes outside that site.
- (6) The quantity manufactured, imported, or processed.

(b) Any claims of confidentiality must accompany the information at the time it is submitted to EPA. The claims must appear on the form on which the information is submitted to EPA and in the manner prescribed on the form. In addition, any claims of confidentiality must be substantiated at the time the information is submitted to EPA in the manner specified in the form instructions.

(c) Any information that is covered by a claim made as specified will be disclosed by EPA only to the extent permitted by, and by means of, the procedures set forth in this section and in Part 2 of this Title (41 FR 36902).

(d) If no claim accompanies information at the time it is submitted to EPA, the information may be made public by

EPA without further notice to the submitter. Failure to provide substantiation of any claim asserted on the forms will be considered a waiver of the claim and will result in a determination that the information is not entitled to confidential treatment.

(e) (1) A claim of confidentiality may be asserted concerning the specific chemical identity of a particular chemical substance. This claim may be asserted by any submitter who believes that inclusion of the specific chemical identity on the inventory would reveal the trade secret fact that the particular chemical substance is manufactured or processed for commercial purposes.

(2) If a submitter asserts such a claim the submitter must

- (i) Report the specific chemical identity.
- (ii) Propose a generic chemical name which is only as generic as necessary to protect the confidential identity of the particular chemical substance.
- (iii) Provide a detailed, written substantiation of the claim as specified in the reporting instructions.

(iv) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture the substance (as defined in paragraph (g) of this section) the fact that the particular chemical substance is included in the inventory for purposes of TSCA section 5(a) (1) (A) premanufacture notification, and

(v) Have available, and agree to furnish to EPA upon request, for the particular chemical substance, either an X-ray diffraction pattern (in the case of inorganic substances) or a mass spectrum for the particular chemical substance (in the case of most other substances), a sample of the substance in its purest form, an elemental analysis, any additional or alternative spectra, or other data that may be required to resolve uncertainties with respect to the identity of the substance. Failure to meet any of these five requirements will be considered a waiver of the claim and will result in inclusion of the particular chemical identity on the inventory.

(f) (1) If a submitter asserts that the identity of a particular chemical substance should not be included on the inventory, the submitter has met the five requirements specified in paragraph

(e) of this section, and the EPA General Counsel has made a determination, in accordance with Part 2 of this Title that the particular chemical identity should not appear on the inventory because inclusion would disclose a trade secret. EPA will publish a generic chemical name in an appendix to the inventory rather than place the specific chemical identity on the inventory. Publication of a generic name in the appendix does not create a category for purposes of the inventory. Any person proposing to manufacture a substance included in the appendix under a generic name must submit notice under section 5(a) (1) (A) of the Act unless specifically exempted by EPA (see paragraph (g) of this section).

(2) EPA will examine the generic

chemical name proposed by the submitter claiming confidentiality.

(i) If EPA determines that the generic name proposed by the submitter asserting the claim is only as generic as necessary to protect the confidential identity of the particular chemical substance, EPA will place that generic name on the inventory.

(ii) If EPA determines that the generic name proposed by the submitter asserting the claim is more generic than necessary to protect the confidential identity, EPA will ask the submitter to submit further proposed generic names.

(iii) If EPA does not agree with the further proposed generic names, EPA will choose a generic name that EPA determines is only as generic as necessary to protect the confidential identity. EPA will give 30 days notice of this choice to the submitter asserting the claim. After the end of the 30-day period EPA will place the chosen generic name on the inventory.

(g) (1) If the particular chemical substance a person is proposing to manufacture is not included on the inventory by specific name but does fall within one of the generic chemical names in the appendix entitled "Confidential Identities," the person may ask EPA whether the specific substance is included on the inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture the substance.

(2) In order to establish a *bona fide* intent to manufacture the specific chemical substance the person proposing to manufacture the chemical substance must submit to EPA:

(i) A signed statement that that person intends to manufacture the substance for commercial purposes,

(ii) A description of the research and development activities he has conducted to date and the purposes for which the substance will be manufactured,

(iii) An elemental analysis,

(iv) Either an X-ray diffraction pattern (in the case of inorganic substances) or a mass spectrum (in the case of most other substances) of the particular chemical substance,

(v) A sample of the substance in its purest form, if requested, and

(vi) Any additional or alternative spectra, or other data that may be required to resolve uncertainties with respect to the identity of the chemical substance.

(3) (i) Upon receipt of the information specified in paragraph (g) (2) of this section, EPA may require the submitter who asserted the confidentiality claim for a specific chemical substance within the generic name to submit to EPA:

(A) Either an X-ray diffraction pattern or a mass or alternative spectrum for the substance,

(B) An elemental analysis of the substance,

(C) A sample of the substance in its purest form, if requested, and

(D) Any additional spectral or other data that may be required to resolve un-

certainities with respect to the identity of the substance.

(ii) Failure to submit any of the information required by EPA under this paragraph (g) (3) will be construed as a waiver of the submitter's confidentiality claim, and EPA will place the specific chemical identity on the inventory without further notice to the submitter.

(4) EPA will compare the information submitted by the proposed manufacturer under paragraph (g) (2) of this section with the information submitted under paragraph (g) (3) of this section.

(5) If (i) the comparison of the elemental analyses and either the X-ray diffraction patterns or mass or alternative spectra is sufficiently similar to be consistent with a presumption that the chemical substances are the same, and (ii) comparison of any of the other submitted information affirms this presumption, EPA will tell the person proposing to manufacture the particular chemical substance that the particular chemical substance is included on the inventory and, therefore, that premanufacture notification is not required.

(6) If (i) the comparison of either the X-ray diffraction patterns or the mass or alternative spectra is not sufficiently similar to be consistent with a presumption that the chemical substances are the same, and (ii) comparison of the other information affirms this conclusion, EPA will tell the person proposing to manufacture the particular substance that the information submitted does not support a conclusion that the substance is included on the inventory, and, therefore, that premanufacture notification is required.

(7) A disclosure to a person with a bona fide intent to manufacture a particular chemical substance will not be considered a public disclosure.

§ 710.8 Effective date.

These regulations shall take effect on January 1, 1978.

APPENDIX A—SIGNIFICANT COMMENTS AND RESPONSES

Over 400 comments were received in response to the notices of proposed rulemaking published in the FEDERAL REGISTER on March 9, August 2, and October 3, 1977. The following summarizes and responds to the significant issues raised in these comments. Comments which concern problems specific to one particular company were not generally included in these comments. These comments were referred to EPA's Industry Assistance Office for direct reply.

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Inventory Reporting Procedures. General, comment 76; Reporting of Polymers, comments 77-82; Inventory Reporting Forms, comments 83-87.

When To Report. Comments 88-92.

Confidentiality. Comments 93-103.

OVERALL APPROACH TO THESE REPORTING RULES

Comment 1: Reporting under these first reporting rules should not only be for the purpose of compiling the inventory required by section 8(b), but also to establish a base line of information for further regulatory action under TSCA. Failure to gather site, production, use, impurity, byproduct, disposal, and worker exposure information in a comprehensive manner precludes a systematic approach to the regulation of chemicals.

Response: The Administrator agrees, in part, with this comment. The August 2, 1977, reproposal expanded the purpose of these regulations as proposed on March 9, 1977. These final regulations are similar to those proposed on August 2nd.

In deciding the scope of these first section 8(a) reporting requirements, EPA considered not only the interest of compiling an inventory of chemical substances as required by TSCA section 8(b), but also the need for obtaining sufficient information for monitoring chemical substances in the environment and setting Agency priorities for implementing other provisions of TSCA. The Agency decided that initial reporting requirements should at least establish a profile of the chemical industry, including sites where chemicals are being manufactured and the relative quantities in which they are produced or imported into the United States. With this information, EPA will be able to estimate the potential exposure to chemical substances for control, and preventive actions. For example, plant site information will be useful in identifying possible sources of hazardous chemicals, especially in an emergency. Data on the quantities of chemical substances manufactured for a commercial purpose will enable EPA and other agencies to select substances for priority attention from among the tens of thousands of chemicals in commerce.

The Agency will not be requiring use, impurity, byproduct, disposal, or worker exposure information in these regulations. The Administrator has determined that this information is not now necessary for all chemical substances manufactured for a commercial purpose, and that the additional burden to industry and consequent delay in publication of the inventory would not be justified. EPA intends, under the authority of section 8(a), to require this additional information on a smaller number of chemicals in order to assess their potential risks in depth. These requirements will be directed at manufacturers and processors of the chemical substances to enable the Agency to build a more complete profile on these chemicals which are of concern.

Comment 2: EPA's proposed approach would require unnecessarily burdensome and needlessly duplicative reporting. EPA should compile and publish a list of chemical substances from government, industry, and other sources, and allow manufacturers and trade associations to report any chemical substances not included.

Response: The Administrator disagrees with this comment. The Agency reviewed existing lists of chemical substances and

found them inadequate in several respects. First, many existing lists contain chemical substances which are not eligible for inclusion on the TSCA inventory. Second, in existing lists, many of the entries are in broad categories or use groups (such as "optical brighteners") which would be inappropriate for the purposes of compiling a list of discrete chemical substances manufactured or processed for a commercial purpose in the United States. Third, existing lists would not permit EPA to identify the basic manufacturers of a chemical substance. The purposes of TSCA, accordingly, would not be met if EPA were simply to publish currently available lists as the inventory of chemical substances and permit manufacturers to report any substance not included.

EPA is interested in minimizing the burden of reporting for the inventory. Accordingly, the Agency has published a Candidate List of Chemical Substances which includes those substances we have reason to believe have been manufactured or processed in the United States. For any chemical substance included on the Candidate List, reporting for the inventory is greatly simplified. By FEDERAL REGISTER notice dated April 28, 1977 (42 FR 21639) and July 8, 1977 (42 FR 35183), the Agency announced the availability of the Candidate List in hard copy and computer readable tape. EPA plans to supplement the Candidate List with at least one additional list of substances. EPA will announce the availability of any additional list in the FEDERAL REGISTER. By FEDERAL REGISTER notice dated April 12, 1977 (42 FR 19298) the Agency published a proposed Guide to the Use of the Candidate List. This Guide will be republished with some changes to assist persons reporting for the inventory. This document and any supplement to the Candidate List will be available from EPA at the address listed above.

In a further effort to minimize duplicative reporting to the extent consistent with the needs of the Agency, § 710.5(f) of these final regulations permits all manufacturers or importers not required to report by § 710.3 (a) (1) and (2) to report chemical substances through a trade association or other agent. Further, any person who processes a chemical substance is only subject to the revised inventory. These policies should eliminate a great amount of duplicative reporting.

Comment 3: Manufacturers should be required to report chemical substances manufactured for a commercial purpose by plant site rather than by company headquarters.

Response: The Administrator agrees with this comment. The March 9, 1977 proposal would only have required manufacturers to report chemical substances by company headquarters. As part of the decision to require reporting of information which will give the Administrator a profile of where chemicals are being manufactured, the August 2, 1977 reproposal would require reporting by plant site. These final regulations continue this requirement. The Agency intends to use this information to monitor for potential exposure and identify possible sources of hazardous chemicals in an emergency.

Comment 4: EPA has failed to demonstrate that production volume data are necessary to compile the inventory, and it is unclear how EPA intends to use this additional information. In emergencies, EPA needs to know where a chemical is produced, not the exact quantity. The delay in publishing the inventory is not justified by the information to be gained by requiring more detailed data.

Response: Production volume information is not being required to publish the inventory under section 8(b). This information is